RO-24-7429

--IN THE CLAIMS--

Please add the following new claim:

21. The composition of claim 1 wherein said TNF inhibitor is thalidomide and said gene inhibitor is a compound having the structure

Pursuant to M.P.E.P. 808.01(a) and 37 C.F.R. 1.141 applicant has elected a single disclosed combination of a TNF inhibitor and a gene inhibitor. Also pursuant to 37

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C.F.R. 1.141(a) the Examiner, upon finding the elected combination patentable, is requested to extend consideration on the merits to additional combinations covered by the claims.

The restriction requirements is respectfully traversed. 35 USC 121 is permissive, not mandatory, and accordingly MPEP 808 requires not only clarification of the reasons why inventions as claimed are independent and distinct but also the reasons for insisting on restriction therebetween. Furthermore, the Commissioners notices appearing in 934 OG 2 and 922 OG 1016 urge examination of an entire application on the merits if this can be made without serious burden on the Examiner, even in cases which includes claims to distinct or independent inventions. Applicant believes that the entire invention as claimed can be examined without serious burden to the Examiner since thalidomide the drug of choice in the present invention is easily searchable in Class 514, subclass 323 and provides unity of invention. MPEP 800 specifically states that if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or indenpendent inventions. Applicant believes that thalidomide is a common link to all the claims.

Applicant respectfully requests and urges the Examiner to examine the present application as a whole. Because of the new GATT rules, it is respectfully requested that thies application be examined in its entirety since it is not clear what the patent office's future policy will be regarding divisional practice.

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Also it is noted that the restriction requirement fails to state that the many inventions are independent and distinct, rather, only distinct.

If, the Patent and Trademark Office intends to divide the present application into a plurality of Examiner-determined inventions and restrict prosecution of the present application to one aspect of the subject matter which Applicant regards as his invention, equity requires that the factual basis for so holding be clearly delineated so that the record will reflect if such a requirement is proper under 35 USC 121.

The importance of the written record clearly setting forth the reasons upon which a restriction requirment is based, particularly with respect to claims to a compound or composition held patentably distinct by the Patent and Trademark Office over method of use claims, is increasingly apparent from a brief filed by the Justice Department in <u>U.S. v. Union Carbide Corp.</u>, and antitrust action in the U.S. District Court for Northern California seeking to invalidate U.S. Patent 3,009,855 on the insecticide "Sevin". In that case, the Patent and Trademark Office has insisted that the original application, claiming both a product and method of use, be restricted and merely alleged that the two constituted "distinct" inventions. Applicants retained product claims in the original application and canceled method claims which were presented in a divisional application. Some 20+ years later, the Justice Department argued in its brief that the restriction requirement was clearly not authorized under 35 USC 121, since the statue imposes the dual criteria that restrictable inventions must be both independent and distinct, stating in its brief:

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...it is clear that the product carbaryl and its only disclosed use, e.g., killing insects, are <u>not</u> "independent and distinct" inventions. Since the first application expressly discloses how to use carbaryl as an insecticide in order to meet the statutory requirements for patentability, it cannot properly be said there is "no disclosed relationship" between the product carbaryl and its disclosed use as an insecticide. Nor can it be correctly said that the product carbaryl is "unconnected in design, operation or effect" with its use to kill insects. Thus it is clear that the restriction requirement which

In view of the above, reconsideration and withdrawal or at least clarification of the election of species requirement and an early action on the merits are courteously requested. A check in the amount of \$11.00 is enclosed to cover the additional dependent claim.

was imposed on the first application lacked authority under 35 USC 121 because that

application did not claim "two or more independent and distinct inventions".

Respectfully submitted,

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And12C2a